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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,745	01/15/2002	Patrick R. Fleming	57453US002	5471

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EXAMINER

THANH, LOAN H

ART UNIT PAPER NUMBER

3763

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,745

Applicant(s)

FLEMING ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 14-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/07/03, 06/10/02</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of GROUP I AND SPECIES I (FIGS. 1-2A) in the reply filed on 03/11/04 is acknowledged. The traversal is on the ground(s) that 1/ it is unclear which of the identified species by figure number correspond with claims" and 2/ the public will be better served if only one patent issues from the enclosed specification. This is not found persuasive because as to 1/ the Examiner has distinctly pointed out the different species/embodiment as applicant has disclosed in the specification. It is applicant's burden to respond with a listing of all the claims readable thereon. See the page 3 of the restriction. With respect to 2/ only one patent is issued for 1 invention. Applicant is reminded that upon allowance of a generic claim , applicant will be entitled to consideration to additional species, which are written in dependent for . see page 3-4 of the restriction. If applicant is arguing that the species are not patentably distinct then applicant should submit evidence or identify such evidence now of record showing the species to obvious variants and clearly admit on the record that this is the case. See page 4 of the restriction.

Claims 4-9,14-35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/11/04.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hydrophilic surface within the capillary volume (claim 10-11) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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Claim Objections

Claims 2-3,10-13 objected to because of the following informalities: The preamble of the dependent claims should refer back to the dependent as "The device" not "A device". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Eicher et al. (WO 97/03718).

Eicher et al. Disclose a microneedle device comprising a substrate 10a,10b, a plurality of microneedle 8, a cover 15 and a capillary volume between the first major and surface of the substrate and the inside side of the cover. See figure 5.

Claims 1-3,10-11 are rejected under 35 U.S.C. 102(e) as being anticipated Yeshurun (US 6,558,361).

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Yeshurun discloses a microneedle device comprising a substrate, a plurality of microneedles (see abstract) a cover 60 and a capillary volume between the substrate and the first/under side of the cover. Yeshurun further discloses a hydrophilic surface within the capillary volume. Yeshurun discloses coating at least the microneedles with metal or metal alloy. (As evidenced by Arias et al. (US 6,663,820). Arias et al. teaches using materials such as Teflon.RTM and metalized surfaces to provide for the designer a freedom of creating hydrophilic-hydrophobic combinations on the microneedle structure).

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated Rosenberg (US 2003/0199812).

Rosenberg discloses a microneedle device comprising a substrate, a plurality of microneedles 24, a cover 14 and a capillary volume between the substrate and the first/under side of the cover.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeshurun (US 6,558,361) in view of Chacornac (US 4,109,655).

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See Yeshurun substantially discloses the claimed invention. See above.

Yeshurun shows a needle with a channel within the microneedle for passage of fluids. However, Yeshurun does not disclose a channel on the outer surface of the microneedle. Chacornac teaches a variation of needles for delivering treatment material to the patient in the analogous art of needles. Chacornac teaches needles with internal channels and needles with channels on the outer surface for passage of material/fluids. See figures 14-24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle channels of Yeshurun with the external channels as taught by Chacornac as a mere design choice of channels which function to delivery treatment material.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT